K123988

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Submitter:
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Device Information:
Device Name: AnyOne™ Internal Implant System
Classification Name: Implant, Endosseous, Root-Form
Common Nmae: Endosseous Dental Implant
Classification: Class II
Product Code: DZE
Subsequent Product Code: NHA
Regulation number: 21 CFR 872.3640
Date Prepared: 11/20/2012

AUG 15 2013

General Description

The AnyOne™ Internal Implant System is especially designed for use in dental implant surgery. It consists of machined titanium, screw-form, root-form endosseous dental implant. The AnyOne™ Internal Implant System contains three types of fixtures, normal thread type, deep thread type, and special length type. This system is made from CP4 Titanium and Ti-6Al-4V-ELI and the surface treatment is done with S.L.A (Sand-blasted, Large grit, Acid-etched). The implants are used to replace missing teeth in various situations ranging from a single missing tooth to the completely edentulous individual. The wide ranges of size are provided to be in conformance with each patient, or to cover up in case of deficiency in implant operation. The system is used as two stage, root-form dental implants, associated with abutment systems, which provide the clinician with the screw and cement retained restoration. This system has 3.9, 4.3, 4.8, 5.3, 6.3, 7.3mm diameters for normal thread, 4.8, 5.8, 6.8, 7.8, 8.3mm diameters for deep thread, and 4.8, 5.3, 6.3, 7.3mm for special length fixtures. In addition, this system has 7.0, 8.0, 9.5, 11.0, 12.5, 14.5mm lengths for normal thread, 7.0, 8.0, 9.5, 11.0, 12.5, 14.5mm lengths for deep thread, and 7.0mm for special length fixtures.

Contained various abutments in the AnyOne™ Internal Implant System are straight and angled dental implant abutments intended to be connected to the fixture with screw, and to restore a patient's chewing function. The abutments contain Cover Screw, Healing Abutment, EZ Post, Angled Abutment, Milling Abutment, Zirconia Abutment, Gold Abutment, CCM Abutment, Temporary Abutment, Solid Abutment,

Burn-out Cylinder, Octa Abutment, Temporary Cylinder, EZ Post Cylinder, Gold Cylinder, CCM Cylinder, Plastic Cylinder, Flat Abutment, Ball Abutment, Meg-Rhein, ZrGEN Abutment, Multi-unit Abutment, Fuse Abutment, Flat CCM Cylinder, Flat Cover Screw, Flat Healing Abutment, Flat EZ Post Cylinder, Flat Temporary Cylinder, Flat Plastic Cylinder, and Flat Gold Cylinder.
The fixtures, prosthetics, and surgical instruments are produced, and packaged separately. All included devices in the system are covered by this submission.

Indication for use
The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.

Predicate devices
- XPEED AnyRidge Internal Implant System (K122231)

Substantial Equivalence Comparison
The AnyOne™ Internal Implant System has a substantially equivalent intended use as the identified predicate. The AnyOne™ Internal Implant System is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium. The subject and predicate device are similar in size and materials.
There is no difference between the subject device and the predicate with respect to indications and technology.

	Subject Device	**Predicate Device**
510(k) Number	Not available yet	K122231
Device Name	AnyOne™ Internal Implant System	XpeedAnyRige Internal Implant System
Manufacturer	MegaGen Implant Co,. Ltd	MegaGen Implant Co,. Ltd
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories

Design	AnyOne™ Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Hex		XpeedAnyRidge Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Hex
Material	CP4 Titanium and Ti-6Al-4V-ELI		CP4 Titanium and Ti-6Al-4V-ELI
Sterilization	Gamma sterilization		Gamma sterilization
Fixture Diameter	Internal type 3.9, 4.3, 4.8, 5.3, 6.3, 7.3mm (for normal thread) 4.8, 5.8, 6.8, 7.8, 8.3mm (for deep thread) 4.8, 5.3, 6.3, 7.3mm (for special length)		Internal type 4.0, 4.4, 4.9, 5.4, 5.9mm (For normal ridge) 6.4, 6.9, 7.4, 7.9, 8.4mm (For low ridge)
Fixture Height	Internal type 7.0, 8.0, 9.5, 11.0, 12.5, 14.5mm (for normal and deep thread) 7.0mm (for special length)		Internal type 7.7, 9.2, 10.7, 12.2, 14.20, 17.2mm (For normal ridge) 7.9, 9.4, 10.9, 12.4, 14.4mm (For low ridge)
Abutment	**Diameters**	Ø 3.8 – 10.0mm	Ø 4.0 – 10.0 mm
	Lengths	7.7 – 18.7mm	8.4 – 16.4 mm
Angulations of Angled abutments	15, 25°		15, 25°
Product Code	DZE, NHA		DZE, NHA
Surface treatment	SLA		SLA

Non-Clinical Test Data

The fatigue testing was performed in accordance with ISO 14801 standard.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification concludes that the AnyOne™ Internal Implant system is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

MegaGen Implant Company, Limited
C/O Ms. April Lee
KoDent, Incorporated
325 North Puente Street, Unit B
BREA CA 92821

Re: K123988
Trade/Device Name: AnyOne™ Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: August 8, 2013
Received: August 12, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K123988

Device Name: AnyOne™ Internal Implant System

Indications for Use:

The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.

Prescription Use _____X_____ **AND/OR OverThe-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.08.15 09:17:05 -04'00'
for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: